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[Docket No. 89E-0085]

**Determination of Regulatory Review Period for Purposes of Patent Extension; Hismanal®**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Hismanal® (astemizole) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESS:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Hismanal® (astemizole). Hismanal® is indicated for the relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria. Hismanal® is not indicated for short courses of therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Hismanal® (U.S. Patent No. 4,219,559) from Janssen Pharmaceutica N.V. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated March 20, 1989, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period. The letter also stated that the active ingredient, astemizole, represented the first permitted commercial marketing or use. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Hismanal® is 2,983 days. Of this time, 1,579 days occurred during the testing phase of the regulatory review period, while 1,404 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* October 31, 1980. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was October 31, 1980.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* February 25, 1985. FDA has verified the applicant's claim that the date the new drug application (NDA) for Hismanal® (NDA 19-402) was initially submitted to FDA was on February 25, 1985.

3. *The date the application was approved:* December 29, 1988. FDA has verified the applicant's claim that NDA 19-402 was approved on December 29, 1988.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, the applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before (*June 9, 1989*), submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before (*October 10, 1989*), for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 1989.

Stuart L. Nightingale,

*Associate Commissioner for Health Affairs.*

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## Health Resources and Services Administration

### Acquired Immune Deficiency Syndrome; Drug Reimbursement Program

**AGENCY:** Health Resources and Services Administration, PHS, HHS.

**ACTION:** Notice of Availability of Funds.

**SUMMARY:** Under the authority of Pub. L. 100-471, an additional $5,000,000 has been made available to States to cover the cost of Zidovudine (AZT), and certain other drugs that have been determined to prolong the lives of persons with Acquired Immune Deficiency Syndrome (AIDS). The $5,000,000 was generated through a reprogramming of funds from other AIDS activities within the Department of Health and Human Services. The reprogramming was a special act by the Congress and the Administration to provide additional funding for those States that reported a shortfall from their previous drug treatment Federal Allotment. In addition, another $75,490 was made available to these States through a redistribution of funds from